

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Study of the effect of Iranian traditional massage (Kermanshahi style) on clinical signs of knee osteoarthritis

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of Kermanshahian Persian massage in relation to knee osteoarthritis.

Design

Blocked Randomization Clinical trial study Sample size 42 for each of the treatment and control groups

Settings and conduct

Patients in the orthopedic clinic of Imam Hossein Hospital, diagnosed mild to moderate arthritis The treatment group undergoes massage therapy by the researcher once a week and daily by the individual. In the control group, liquid paraffin is supplied to patients for daily use. The duration of the study is 6 weeks and the WOMC and VAS questionnaires are completed at the beginning and after 3 and 6 weeks and 2 weeks after the completion of the treatment.

Participants/Inclusion and exclusion criteria

Inclusion: 40 to 80 year old patients with mild to moderate osteoarthritis Exclusion: Secondary osteoarthritis to rheumatoid diseases, History of Surgery on the knee, BMI higher than 35, Intra-articular or oral corticosteroid ingestion in the 3 months before and 2 weeks before, Pregnancy and breastfeeding

Intervention groups

The treatment group undergoes Kermanshahi's massage style The control group, uses liquid paraffin for daily rubbing on the knee

Main outcome variables

VAS; WOMAC Pain; WOMAC Stiffness; WOMAC Physical Function; WOMAC Total; Number of Acetaminophen 500 per day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190121042438N1**

Registration date: **2019-09-21, 1398/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-24, 1398/07/02**

Update count: **1**

Registration date

2019-09-21, 1398/06/30

Registrant information

Name

SaraSadat SeyedEsfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

esfahani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2020-01-10, 1398/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Iranian traditional massage (Kermanshahi style) on clinical signs of knee osteoarthritis

Public title

Study of the effect of traditional massage on the

symptoms of knee osteoarthritis

IR.SBMU.RETECH.REC.1397.829

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All 40 to 80 year old patients with mild to moderate osteoarthritis (according to ACR criteria) referring to Imam Hossein Orthopedic Clinic

Exclusion criteria:

Secondary osteoarthritis due to rheumatologic diseases
History of Surgery on the affected knee BMI higher than 35
Intra-articular or oral corticosteroid ingestion in the 3 months before and 2 weeks before Pregnancy and breastfeeding

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomization with the help of computer software

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of medical sciences Aarabi St Yemen Ave. Chamran Highway Tehran Iran

City

Tehran

Province

Tehran

Postal code

1516745811

Approval date

2019-01-08, 1397/10/18

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

2

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Score of knee pain intensity

Timepoint

Before the intervention, weeks 3 and 6 , and 2 weeks after the intervention

Method of measurement

Visual Analogue Scale and Western Ontario and McMaster universities osteoarthritis questionnaire

2

Description

Score of knee Stiffness intensity

Timepoint

Before the intervention, weeks 3 and 6 , and 2 weeks after the intervention

Method of measurement

Western Ontario and McMaster universities osteoarthritis questionnaire

Secondary outcomes

1

Description

score of daily physical activity

Timepoint

Before the intervention, weeks 3 and 6 , and 2 weeks after the intervention

Method of measurement

Western Ontario and McMaster universities osteoarthritis questionnaire

2

Description

Number of Acetaminophen tab 500mg used

Timepoint

At the beginning of the intervention, weeks 3 and 6

Method of measurement

Question from patient

Intervention groups**1****Description**

Intervention group: Six weeks of weekly massage with chamomile oil by the researcher and daily massage by the patient

Category

Rehabilitation

2**Description**

Control group: Six weeks of daily oil rubbing with liquid paraffin

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Hosein Hospital

Full name of responsible person

Mahmood Khodadoost

Street address

Madani St.

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1617763141

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Mahmood Khodadoost

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No,8, Shams Alley, Opposite Tavanir, Valiasr Ave.

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Web page address

http://traditional.sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

SaraSadat SeyedEsfahani

Position

Phd student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahmood Khodadoost

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patients have been given consent for information confidentiality.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available